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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,376	07/02/2001	Frank D. Hong	UTSC:645US/SLH	2755

7590 01/13/2003

FULBRIGHT & JAWORSKI L.L.P.
SUITE 2400
600 CONGRESS AVENUE
AUSTIN, TX 78701

[REDACTED] EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,376	HONG ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 October 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 and 16-85 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 7-15 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7&8</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I in Paper No. 10 is acknowledged. No claims have been added or canceled. Claims 1-85 are pending, claims 4-6, 16-85 are withdrawn from consideration as being drawn to a non-elected invention, therefore, claims 1-3, and 7-15 are examined on the record.
2. Claims 4-6 and 16-85 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invnetions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10. Applicant is reminded to cancel all non-elected claims.

Information Disclosure Statement

3. The information disclosure statements filed 10/21/2001 and 6/17/2002 (paper nos. 7 & 8) are acknowledged and considered. A signed copy is attached hereto.

Drawings

4. Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first

Art Unit: 1642

paragraph of the brief description of the drawings section of the specification which states:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Claim Rejections - 35 USC § 112, 2nd paragraph

5. Claims 1-3, 7-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Regarding claims 1, 7, and dependent claims thereof in the recitation of the term "peptide" and "drug" it is unclear and indefinite because the intended peptide of claim 1 and 7 and the drug of claim 7 is not defined. Furthermore, it is unclear whether the peptide or drug is effective and used for all types of tumors. Correction and clarification are required.

Claim Rejections - 35 USC § 112, 1st paragraph

7. Claims 1-3, 7-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a peptide consisting of SEQ ID No: 1 that is capable of internalizing into a cell, does not reasonably provide enablement for any peptide that is capable of internalizing into a tumor cell. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The nature of the invention: The invention is drawn to a peptide and a composition comprising a peptide and a drug.

The amount of direction or guidance present and the presence or absence of working examples: The examples of the instant invention disclose the identification of a peptide,

the internalization of the peptide, and the localization of the peptide within a tumor of which said peptide is identified as SEQ ID No: 1. There is, however, no mention of any other sequences or peptide other than that of SEQ ID No: 1 or HN-1 peptide. Because the claim recites a broad scope of peptides and compositions in general, one of skill would not know where to begin the screening of a peptide that is capable of internalizing into a tumor cells. Because there are numerous peptides that may be able to perform this task, and because there is a lack disclosure to adequately guide one of skill in the art to make or use the claimed peptide, one of skill would be forced into undue experimentation to make and or practice the invention.

The breadth of the claims and the quantity of experimentation needed: Given the broad range of peptides and compositions encompassed within the claims, which includes proteins, antibody fragments, peptide conjugates, and small peptides, it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 7, 10-13, and 15 rejected under 35 U.S.C. 102(b) as being anticipated by WO 88/00837 (Myers A et al) and US Patent No. 5,087,616 (Myers A et al). Claims

Art Unit: 1642

1,7,10-13, and 15 are drawn to a peptide that is capable of internalizing into a tumor cell and a composition comprising the said peptide and a drug, wherein said drug is selected from the group consisting of a chemotherapeutic agent, cytotoxic agent, apoptotic agent, DNA damaging agent, and chemotherapeutic agents of which include cisplatin. Myers *et al* (WO 88/00837 and US Pat. No. 5,087,616) teach a peptide that is capable of internalizing into a tumor cell and further teach a composition comprising said peptide and a drug, wherein the drug could be a chemotherapeutic agent, a cytotoxic agent, an apoptotic agent, a DNA damaging agent, and a chemotherapeutic agents of which is cisplatin.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1, 7, 10-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Blaschuk *et al* (US Pat No. 6,303,576). Claims 1,7, and 10-15 are drawn to a peptide that is capable of internalizing into a tumor cell and a composition comprising the said peptide and a drug, wherein said drug is selected from the group consisting of a

chemotherapeutic agent, cytotoxic agent, apoptotic agent, DNA damaging agent, Taxol, and chemotherapeutic agents of which include vinca alkaloids. Blaschuk *et al* teach a peptide that is capable of internalizing into tumor cells, and a composition that comprises said peptide and a drug, wherein said drug is selected from the group consisting of a chemotherapeutic agent, cytotoxic agent, apoptotic agent, DNA damaging agent, Taxol and chemotherapeutic agents which includes vinca alkaloids.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Application/Control Number: 09/899,376

Page 8

Art Unit: 1642

Christopher Yaen
Art Unit 1642
January 13, 2003

Arc
ALI R. SALIMI
PRIMARY EXAMINER